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FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. FILING DATE APPLICATION NO. David Hung 05284.00096 09/912,499 07/26/2001 **EXAMINER** 38732 03/02/2004 7590 CYTYC CORPORATION SIRMONS, KEVIN C 85 SWANSON ROAD ART UNIT PAPER NUMBER BOXBOROUGH, MA 01719 3763 W

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

	Application No.	Applicant(s)	~
•	09/912,499	HUNG, DAVID	
Office Action Summary	Examiner	Art Unit	
•	Kevin C. Sirmons	3763	
The MAILING DATE of this communication app Period for Reply	pears on the cover sheet with the c	correspondence address	_
A SHORTENED STATUTORY PERIOD FOR REPL' THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a repl - If NO period for reply is specified above, the maximum statutory period of the period for reply within the set or extended period for reply will, by statute any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be tir y within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from t, cause the application to become ABANDONE	nety filed rs will be considered timety. Ithe mailing date of this communication. CD (35 U.S.C. § 133).	
Status		·	
1) Responsive to communication(s) filed on 12 J	anuary 2004.		
2a) ☐ This action is FINAL . 2b) ☑ This	☐ This action is FINAL. 2b)☑ This action is non-final.		
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is			
closed in accordance with the practice under E	Ex parte Quayle, 1935 C.D. 11, 4	53 O.G. 213.	
Disposition of Claims			
4) Claim(s) <u>1-13,26 and 27</u> is/are pending in the	application.		
4a) Of the above claim(s) is/are withdrawn from consideration.			
5) Claim(s) is/are allowed.			
6)⊠ Claim(s) <u>1-8</u> is/are rejected.			
7)⊠ Claim(s) <u>9-13</u> is/are objected to.			
8) Claim(s) are subject to restriction and/o	or election requirement.		
Application Papers			
9) The specification is objected to by the Examine	er.		
10) The drawing(s) filed on is/are: a) acc	epted or b) objected to by the	Examiner.	
Applicant may not request that any objection to the	drawing(s) be held in abeyance. Se	e 37 CFR 1.85(a).	
Replacement drawing sheet(s) including the correct			
11)☐ The oath or declaration is objected to by the Ex	xaminer. Note the attached Office	e Action or form PTO-152.	
Priority under 35 U.S.C. § 119	•		
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:	priority under 35 U.S.C. § 119(a)-(d) or (f).	
1. Certified copies of the priority documents have been received.			
2. Certified copies of the priority documents have been received in Application No			
3. Copies of the certified copies of the prio	· ·		
application from the International Burea	u (PCT Rule 17.2(a)).		
* See the attached detailed Office action for a list	of the certified copies not receive	ed.	
Attachment(s) 1) Notice of References Cited (PTO-892)	4) Interview Summary	(PTO-413)	
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail D	ate	
 Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 	5) Notice of Informal F	Patent Application (PTO-152)	

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DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the means to measure a quality of the ductal fluid in situ and a MEMS must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 rejected under 35 U.S.C. 102(b) as being anticipated by Pestes et al U.S. Pat. No. 5,623,942.

Pestes discloses a flexible probe (12) having a diameter sized to access a breast duct (12) and a distal portion being capable of contacting an interior lumen of a breast duct and retrieving a sample of the breast duct fluid from within the duct for analysis (distal end of 10),

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and wherein said probe is free of an opening through which a fluid form an external source can be introduced into said probe and pass through said probe into the duct when said probe is positioned within the breast duct (fig. 1); as to claims 2-6, (distal end of 10).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7-8, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pestes U.S. Pat. No. 5,623,942 in view of Nicholson et al U.S. Pat. No. 4,616,656.

Pestes discloses a device for collecting breast duct fluid substantially as claimed except for a means (marker/indicia) to measure a quality of the ductal fluid in situ. Nicholson et al discloses a means (marker/indicia) to measure a quality of the ductal fluid in situ (col. 4. lines 12-17). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the distal portion of Pestes with the means to measure a quality of the ductal fluid as taught by Nicholson for providing markings to indicate the depth of the device distal end when anchored. Note: applicant indicates that his quality/means can comprise a marker (page 4, line (8).

Pestes discloses a device for collecting breast duct fluid substantially as claimed except for a probe diameter between 0.008 cm to about 0.045 cm. Pestes discloses a probe with a diameter 0.08 cm. It would have been an obvious matter of design choice to one having ordinary skill in the art at the time the invention was made to have various diameter of the probe,

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since it has been held that such a modification would have involved a mere change in the size of

a component. A change in size is generally recognized as being within the level of ordinary skill

in the art. Furthermore, applicant has not disclosed that the various diameters solves any stated

problem in the art or is for any particular purpose and it appears that the invention of Pestes

would perform equally well.

Allowable Subject Matter

Claims 9-13 are objected to as being dependent upon a rejected base claim, but would be

allowable if rewritten in independent form including all of the limitations of the base claim and

any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703) 306-5410. The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.

Kevin C. Sirmons

Patent Examiner

2/19/03

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